BK030031

Section 8- 510(k) Summary of Safety and Effectiveness

8.1 Statement	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92
8.2 Submitter	Haemonetics Corporation 400 Wood Road Braintree, MA. 02184-9114
8.3 Company Contact	Susan Finneran RA Product Manager 355 Wood Road Braintree, MA. 781-356-9220
8.4 Device Name	**Proprietary Name:** Haemonetics® Model 215 Automated Glycerolization / Deglycerolization and Cell Washing System **Common Name:** ACP 215 **Classification Name:** Processing System for Frozen Blood
8.5 Predicate Legally Marketed Devices	The Haemonetics ACP 215, which is the subject of this submission, is substantially equivalent to the previously cleared ACP 215 cleared via BK000002 on May 4, 2001 by Haemonetics Corporation.

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8.6 Device Description	The ACP 215 is an automated cell processing system intended to be used glycerolize ,deglycerolize, and wash red blood cells.

8.7 Device Indications and Intended use	**Indications for use:** The ACP 215 is intended to glycerolize and deglycerolize red blood cells derived from whole blood that have been stored in any approved anticoagulant/additive solution for 6 days at 1-6°C. Red blood cells glycerolized and deglycerolized by the ACP 215 collected in CPDA-1 may be labeled for extended storage for 14 days when stored in Haemonetics AS-3 at 1-6°C. Red blood cells collected in any other anticoagulant / additive solution will be labeled with a 24-hour outdate. ***The ACP 215 is also intended to wash red blood cells that have been collected and stored in CPDA-1 for 21 days or has been stored in CPD/AS-1, CP2D AS-3, CPD/AS-5 for up to 28 days. Re d blood cells washed by the ACP 215 have a 24-hour outdate.***

The following page contains a table comparing the new versus the predicate device.

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8.1 TABLE OF SUSTANTIAL EQUIVALENCE

Characteristics	**Predicate Device** **ACP 215 System**	**Proposed Device –** **ACP 215 System for Cell Washing**
Protocol	Automated Glycerolization/ Deglycerolization	Automated Cell Washing
Hardware	ACP 215	ACP 215
Disposable	LN 225-00 and LN235-00	LN235-00
Washing Solution	12 %NaCl 0.9% NaCl/ 0.2gm Glucose	0.9%NaCl/ 0.2gm Glucose
Intended Use	The ACP 215 is intended to Glycerolize and Deglycycerolize Red blood Cells up to Six days old. Cells collected and stored in CPDA-1 may be labeled for extended storage up to 14 days. Cell collected in other solutions may be stored for 24 hours post-deglycerolization.	When the Cell wash protocol is added the intended use will be amended to include the following statement: *The ACP 215 is also intended to wash red blood cells that have been collected and stored in CPDA-1 for 21 days or has been stored in CPD/AS-1, CP2D AS-3, CPD/AS-5 for up to 28 days. Re d blood cells washed by the ACP 215 have a 24-*hour *outdate.*
Product Quality	**Recovery:** 95% confidence that 90% units met the 80% minimum recovery **Hemolysis:** 95% confident that at 90% of the units met the maximum hemolysis of 1%	**Recovery:** 95% confidence that 90% units met the 80% minimum recovery **Hemolysis:** 95% confident that at 90% of the units met the maximum hemolysis of 1%
Post-Washing Storage	14-days post deglycerolization storage.	24-hours post-wash storage only.

Applicant _____ Date 5/9/03